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RESEARCH**

APPLICATION NUMBER:

40168

CHEMISTRY REVIEW(S)

1. CHEMISTRY REVIEW NO. 2

2. ANDA # 40-168

3. NAME AND ADDRESS OF APPLICANT

Morton Grove Pharmaceuticals, Inc.
6451 West Main Street
Morton Grove, IL 60053

4. LEGAL BASIS FOR SUBMISSION

See Chemist's Review #1

5. SUPPLEMENT(s)

Original 9/20/96

6. PROPRIETARY NAME

N/A

7. NONPROPRIETARY NAME

Hydrocortisone and Acetic Acid

8. SUPPLEMENT(s) PROVIDE(s) FOR:

N/A

9. AMENDMENTS AND OTHER DATES:

Amendment 11/27/95
Amendment 12/21/95
Amendment 7/17/96
Amendment 8/5/96

10. PHARMACOLOGICAL CATEGORY

Treatment of superficial infections of the external auditory canal

11. Rx or OTC

Rx

12. RELATED IND/NDA/DMF(s)

DMF's

13. DOSAGE FORM

Solution

14. POTENCY

1%/2%

15. CHEMICAL NAME AND STRUCTURE

Acetic Acid and Hydrocortisone: Pregn-4-ene-3,20-dione,
11,17,21-trihydroxy-(11B)

16. RECORDS AND REPORTS

17. COMMENTS

18. CONCLUSIONS AND RECOMMENDATIONS

The Application is Approvable PENDING ACCEPTABLE EER.

19. REVIEWER: DATE COMPLETED:

Nashed E. Nashed, Ph.D. 8/9/96

Supervisor: Paul Schwartz, Ph.D. 8/12/96